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EXAMINER

FORD, JOHN M

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/24732

Applicant(s)

Vincenzo

Examiner

J.M. Ford

Group Art Unit

1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on July 31, 2003
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1--P is/are pending in the application.
- Of the above claim(s) 2--1P is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1--P is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Applicant's response of July 31, 200~~2~~<sup>3</sup>, is noted.

The rejections of record continue.

Claim 1 is rejected under 35 U.S.C. 112, 1<sup>st</sup> paragraph. Applicants claim a heteroaryl ring in R2 considerably beyond their support. Applicant need to insert at that point in R2, at the top of page 3 of the most recent response, that the C5-C7 monocyclic heteroaryl ring is selected from the group consisting of

pyridine, pyrazine, pyridazine, pyrimidine, thiophene, pyrrole, pyrazole, imidazole, oxazole or isoxazole ring, unsubstituted or optionally substituted by one or two substituents selected from halogen, CF<sub>3</sub>, C<sub>1</sub>-C<sub>4</sub> alkyl, OH and C<sub>1</sub>-C<sub>4</sub> alkoxy;

Claims 2 and 3 are rejected solely as they are dependent on a rejected claim.

Claim 4 is rejected, as it does not comply with Rule 141. Claim 4 should be rewritten as several claims, each not being more than one page long.

Claim 5 is rejected for the reason claim 1 was, and the remedy is as noted in claim 1, to indicate what rings are intend for heteroaryl in R2.

Claims 6 and 7 are rejected solely as they are dependent on a rejected claim.

Claim 8 does not comply with 37 CFR 1.141 an as indicated. Claim 8 should be rewritten as several claims, each not more than one page long.

Claim 9 is not allowable for the reason claim 1 was rejected, plus the utility stated in claim 9 is not acceptable, as it is not a real world utility.

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Claims 9—12 should be cancelled, as they do not recite a Real World Utility.

A condition medicated by the  $\alpha$ v B3 integrin in a mammal is not an acceptable utility.

Brenner v. Manson, 148 USPQ 689, requires that utility be developed to a point where “specific benefits exist in currently available form”. Similar is the “immediate benefit to the public” standard that Nelson v. Bowler, 206 USPQ 880 refers to “whether the invention has been brought to such perfection as to be capable of practice employment”. This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

A broad disclosure of utility as in the cited claims cannot be deemed in compliance with 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph.

The PTO has amended the guidelines to clarify “specific utility”.

The Court focused on the fact that the applicant failed to identify a “specific utility” in Brenner v. Manson (*above*).

A condition medicated by the  $\alpha$ vB3 integrin could not be considered one disease, or translated from the Laboratory to a Real World Disease.

Applicants need to pick one real World disease from claims 13 or 14.

Failure to elect and amend the claims to one specific, demonstratable utility, from claims 13 or 14 will result in claims 9—14 being held with drawn.

MPEP 806.05(h) provides for restricting out the method claims, altogether, where the compound may be used for more than one purpose. Claims 13 and 14 become evidence claims to the allegation.

This requirement of one specific utility is consistent with Unity of Invention Practice in International Applications and National Phase Applications under U.S.C. 371, and PCT Rule 13.2 for PCT applications.

Therefore, applicants should limit the method claims 13 or 14 to a "specific utility".

Examples of utility expressions that have been held to be insufficient are:

A disclosure that the claimed compounds can be used for "technical and pharmaceutical purpose" does not meet the requirements of 35 U.S.C. 112. In re Kirk et al. (CCPA 1967) 376 F2d 936, 153 USPQ 48.

The how to use "requirements of 35 U.S.C. 112 are not met by disclosing only a pharmacological activity of the claimed compounds, if one skilled in the art would not be able to use the compounds effectively without undue experimentation. In re Diedrich, 138 USPQ 128.

Claims 15—18 are not of the same scope, as claim 1 here, as they recite additional active ingredients. Claims 15—18, therefore, would not be examinable here, as they would require additional searching as such claims are not classified with the compound itself, and stand withdrawn as being a separate invention.

Applicants may not petition the holding of certain claims withdrawn, as the restriction requirement has not been made Final. See 37 CFR 1.144.

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Heteroaryl of one to three heteroatoms selected from O, S and N in claims 1, and 5 is rejected under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as well, as ~~the~~<sup>that</sup> type of expression was held unclear in In re Wiggins, 179 USPQ 421 at 423 (CCPA 1973) which was cited favorably in In re Oetiker, 23 USPQ 2<sup>nd</sup> 1661, CAFC (1991) as the scope of the expression is unclear, as it rests specific conception of what the intended heteroaryl ring is intended to be, *with the reader.*

The heteroaryl term is not acceptable, as it reads on heterocyclic rings that are not set forth <sup>*in the claim*</sup> and require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed must be set forth in the claim.

See page 10 of the specification. Compare breadth.

Conception of what <sup>*he*</sup> intended heteroaryl ring, may be, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately definite to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention there are in reality only two basic reasons for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication

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of the scope of the subject matter embraced by claim; this ground finds its basis in the second paragraph of section 112; second is that the language is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure; this ground stems from the first paragraph of section 112, merits of language in claim must be tested in light of these two requirements. Heteroaryl does not meet either requirement. <sup>the</sup>

heteroaryl variable is not precise and precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim.

The heteroaryl concept is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by the specification. See page 10 of the specification. Conception should not be the role the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53. The heterocyclic rings possible is wide open to staggering possibilities Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, Tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced. Conception of what the intended heterocyclic ring, may be, should not be left to the reader. One needs to know exactly where, in the ring, the heteroatoms are: 1,2 or 1,3 or

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1,4 or 1,2,4 or 1, 3, 4, etc., as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed. One, on reading the indication of heterocyclic applied by applicant, has no idea where the hetero atoms are in this unknown ring. Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language? The heterocyclic term presents a problem of lack of clear claiming, and support in the specification for the variables sought. This rests conception with the reader. What exactly is intended, and where is that supported in the specification? See page 10 of the specification. The possible combinations <sup>of</sup> 1—3 hetero atoms <sup>for instance</sup> in any combination, in multiple size rings is require large, and not shown by applicants to be available starting materials. A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here. It is not possible to classify and search the molecule unless one knows exactly which heterocyclic ring is being claimed. The utility here is a pharmaceutical use. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicant's breadth of heterocyclic claims many different heterocyclic rings. Applicants need to claim what they have demonstrated as a specific fact. The heterocyclic expressions in claim 1 are not acceptable, as they do not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting



material for the rings which applicant now claims. One must be able to tell from a simple reading of the claim what it does and does not encompass. Why?

Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound is being claimed.

The specification serves various purposes. It sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

Therefore, applicants need to indicate in the claim what they intend in clear, concise, language.

Heteroaryl is a huge area of Chemistry. that completely overshadows the formula I, and would be searched, separately, where the heteroaryl is classified.

The heteroaryl term is not set forth in clear, specific language. The reader must produce the heterocyclic ring, in question.

The claims need be amended to reflect the support.

The claims measure the invention. *United Carbon Co. v. Binney & Smith Co.* 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

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The U.S. Court of Claims held to this standard in *Lockhead Aircraft Corp. vs. United States*, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The C.C.P.A. in 1978 "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": *In re Priest*, 199 U.S.P.Q. 11 at 15.

Claim 8 is rejected as a result of the use of the word "prodrug" in line 2 of the claim 8. Thus is no antecedent basis for this word in claim 5. Therefore, claim 8 is rejected under 35 U.S.C. 112, 4<sup>th</sup> paragraph.

It is an entire "other" invention to determine what the "prodrug" would be. What compound fed to a mammal would result in the instant compound(s) that could be <sup>a</sup>life's work!

Prodrug does not comply with either 35 U.S.C. 112, 2<sup>nd</sup> or 1<sup>st</sup> paragraphs. What is it, and where is it supported?

John M. Ford:jmr

September 24, 2003



JOHN M. FORD  
PRIMARY EXAMINER

